Food and Drug Administration, HHS

§ 866.3870

Trypanosoma spp. serological reagents.

(a) Identification. Trypanosoma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Trypanosoma spp. in serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genus Trypanosoma. Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute form of trypanosomiasis in children, most seriously affects the central nervous system and heart muscle.

(b) Classification. Class I (general controls).